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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,669	12/19/2000	R. Allyn Forsyth	ELITRA.009A	7061

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	14

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/741,669	R. A. Forsyth et al.
Examiner	**Group Art Unit**
Frank Lu	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-131 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-131 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Detailed Action

Office Action Summary

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 9, 66, and 124, drawn to a purified or isolated nucleic acid sequence (1-4, 9, and 124) and a preparation comprising an effective concentration of an antisense nucleic acid (claim 66), classified in class 536, subclass 23.1.

II. Claims 5, 10, 12-14, 66, and 67, drawn to a purified or isolated nucleic acid comprising a fragment (claims 5, 10, 66, and 67) and sequence with at least 70% identity to and complementary to purified or isolated nucleic acid (claims 13 and 14), a classified in class 536, subclass 23.1. .

III. Claims 6-8, 11, and 15-17, drawn to a vector comprising a promoter operably linked to the nucleic acid sequence (6-8, 11, 15, and 17), classified in class 435, subclass 320.1; a host cells containing the vector, classified in class 435, subclass 252.3.

IV. Claims 18-21, drawn to a purified or an isolated polypeptide, classified in class 530, subclass 350.

V. Claim 22, drawn to an isolated antibody, classified in class 424, subclass 130.1.

VI. Claim 23-25, drawn to a method of producing a polypeptide, classified in class 435, subclass 69.1.

VII. Claims 26 and 27, drawn to a method for inhibiting proliferation of a microorganism, classified in class 435, subclass 7.2.

VIII. Claims 28-35, 37, and 128, drawn to a method for identifying a compound which influences the activity of a gene product required for proliferation, classified in class 435, subclass 7.1.

IX. Claims 36, 44, 57, 95, 98, 109, 117, 125, and 126, drawn to a compound, classified in class 536, subclass 1.

X. Claims 38-43 and 128, drawn to and a method for identifying a compound or nucleic acid having the ability to reduce the activity or level of a gene product required for proliferation, classified in class 436, subclass 94.

XI. Claims 45-56 and 128, drawn to a method for identifying a compound which reduces the activity or level of a gene product required for proliferation of a microorganism, classified in class 435, subclass 7.2.

XII. Claims 58-65, drawn to a method for inhibiting cellular proliferation, classified in class 436, subclass 94.

XIII. Claims 68-79, drawn to a method for inhibiting the activity or expression of a gene in an operon required for proliferation, classified in class 436, subclass 94.

XIV. Claims 80-83, drawn to a method for identifying a gene which is required for proliferation of a microorganism, classified in class 435, subclass 7.2.

XV. Claims 84-94, 96, 97, and 128, drawn to a method for identifying a compound having the ability to inhibit proliferation of a microorganism, classified in class 435, subclass 7.2.

XVI. Claims 99-108 and 128, drawn to a method for identifying a compound having the activity against a biological pathway required for proliferation, classified in class 436, subclass 94.

XVII. Claims 110-116 and 128, drawn to a method for identifying a compound having the ability to inhibit proliferation, classified in class 436, subclass 94.

XVIII. Claims 118-120, drawn to a method for identifying the biological pathway in which a proliferation required gene or its gene product lies, classified in class 436, subclass 94.

XIX. Claims 121-123, drawn to a method for determining the biological pathway in which a test compound acts, classified in class 436, subclass 94.

XX. Claims 127 and 128, drawn to a method for manufacturing an antibiotic, classified in class 436, subclass 7.1.

XXI. Claims 129-131, drawn to a method for inhibiting proliferation of a microorganism in a subject, classified in class 435, subclass 7.2.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I, II, III, IV, V, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these invention are directed to different nucleic acids that have different modes of operation, different functions, or different effects and are required to perform different searches, and isolated polypeptide, antibody, and compound which have different classification.

Groups I, II, III, V, and IX, and Groups VI and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these invention are directed to different products (nucleic acids, antibody, and compound in I, II, III, V, and IX) and two unrelated method (Groups VI and XX) which are required to perform different searches.

Groups I, II, and III, and Groups VII, VIII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as any method in Groups VII, VIII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, and XXI.

Group IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, that the product as claimed can be made by another and materially different process such as direct synthesis.

Group IV and Groups VII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a product and 13 unrelated methods that have different modes of operation, different functions, or different effects and are required different searches.

Group IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as producing an antibody.

Group V and Groups VII, VIII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a product and 14 unrelated methods that have different modes of operation, different functions, or different effects and are required different searches.

Group VII and Groups VIII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a method for producing a polypeptide (Group VII) and 13 unrelated methods (Groups VIII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX and XXI) that have different modes of operation, different functions, or different effects and are required different searches.

Group VIII and Groups VII, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a method for producing a polypeptide (Group VIII) and 12 unrelated methods (Groups X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX and XXI) that have different modes of operation, different functions, or different effects and are required different searches.

Groups IX and Groups VIII, X, XI, XV, XVI, and XVII, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §

806.05(f)). In the instant case, the product as claimed such as polypeptide in Group VIII can be made by another and materially different process such as the method in Group VI.

Group IX and Groups XII, XIII, XIV, XVIII, XIX, XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to a method for producing a polypeptide (Group IX) and 7 unrelated methods (Groups XII, XIII, XIV, XVIII, XIX, XX and XXI) that have different modes of operation, different functions, or different effects and are required different searches.

Group X and Groups XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX, and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different methods that have different modes of operation, different functions, or different effects and require different searches.

Groups XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XIX, XX, and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different methods that have different modes of operation, different functions, or different effects and require different searches.

4. Sequence Election Requirement Applicable to All Groups

Each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein as evidenced by the methods of at least Group X. Therefore, applicant must further elect a single SEQ ID NO. (See MPEP 803.04). Applicant is advised that examination will be restricted to only elected SEQ ID NO. and should not to be construed as a species election.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

(1) enzymatic activity (claim 29)

(2) carbon compound catabolism activity (claim 30)

(3) biosynthetic activity (claim 31)

(4) transport activity (claim 32)

(5) transcriptional activity (claim 33)

(6) DNA replication activity (claim 34)

(7) cell division activity (claim 35)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1-28 and 36-131.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

(1) said activity is translation of said messenger RNA (claim 39)

(2) said activity is transcription of a gene (claims 40 and 41)

(3) said activity is processing or fold of said nontranslated RNA (claim 42)

(4) said activity is assembly of said nontranslated RNA into a protein/RNA complex (claim 42)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1-38 and 43-131.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

(1) introducing a plasmid (claim 70)

(2) introducing a phage (claim 71)

(3) expressing an antisense nucleic acid (claim 72)

(4) introducing a promoter (claim 73)

(5) introducing a retron (claim 74)

(6) introducing a ribozyme (claim 75)

(7) introducing a liposome (claim 76)

(8) electrophoresis (claim 77)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1-69 and 78-131.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

(1) bacteria cells (claims 47-50, 61-64, and 101-104)

(2) fungal cells (claims 47, 61, and 101)

(3) plant cells (claims 47, 61, and 101)

(4) animal cells (claims 47, 61, and 101)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are 1-46, 51-60, 65-100, and 105-131.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
June 29, 2002